

Translation

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 25628P WO	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/EP2002/007299	International filing date (<i>day/month/year</i>) 02 July 2002 (02.07.2002)	Priority date (<i>day/month/year</i>) 03 July 2001 (03.07.2001)
International Patent Classification (IPC) or national classification and IPC A61K 31/28, 31/30, 31/315, 31/295, C07F 1/08, 3/06, 15/04, 15/06, 15/02, 13/00, 11/00		
Applicant HAEMATO-BASICS GMBH		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of <u>5</u> sheets, including this cover sheet. <input checked="" type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT). These annexes consist of a total of <u>2</u> sheets.
3. This report contains indications relating to the following items: I <input checked="" type="checkbox"/> Basis of the report II <input type="checkbox"/> Priority III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability IV <input type="checkbox"/> Lack of unity of invention V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI <input type="checkbox"/> Certain documents cited VII <input type="checkbox"/> Certain defects in the international application VIII <input type="checkbox"/> Certain observations on the international application

Date of submission of the demand 11 December 2002 (11.12.2002)	Date of completion of this report 16 October 2003 (16.10.2003)
Name and mailing address of the IPEA/EP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/EP2002/007299

I. Basis of the report

1. With regard to the elements of the international application:*

- ☐ the international application as originally filed
- ☒ the description:
pages _____ 1-41 _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____
- ☒ the claims:
pages _____, as originally filed
pages _____, as amended (together with any statement under Article 19
pages _____, filed with the demand
pages _____ 1-6 _____, filed with the letter of _____ 19 August 2003 (19.08.2003)
- ☒ the drawings:
pages _____ 1/12-12/12 _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____
- ☐ the sequence listing part of the description:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/EP 02/07299

I. Basis of the report

1. This report has been drawn on the basis of *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.)*:

The subject matter of the application has been newly directed to the use of a pharmaceutical composition containing at least one complex, D₂-M-T, for producing an antitumor agent and to pharmaceutical compositions according to Claims 5 and 6.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/EP 02/07299

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-6	YES
	Claims		NO
Inventive step (IS)	Claims	1-6	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-6	YES
	Claims		NO

2. Citations and explanations

Prior art:

The search report citations are numbered D1 to D17 according to their order in the search report.

i. Novelty (PCT Article 33(2))

The documents cited as relevant in the international search report are relevant for the assessment of the patentability of the originally submitted claims. Owing to the new version of the claims, which are directed to the use of a pharmaceutical composition and to the pharmaceutical compositions according to Claims 5 and 6, D1 to D17 can be newly evaluated.

The rewording of the claims invalidates the relevance of the cited documents for the original Claims 1 to 8. The prior art discloses compounds which fall into the scope of the originally submitted complex claims, but which have nothing to do with tumor therapy. Claims 5 and 6 are novel because the compounds that fall into the scope of these claims are not disclosed in the prior art.

ii. Inventive step (PCT Article 33(3))

D16 is regarded as the closest prior art, since that document is directed to tumor therapy.

D16 discloses the antitumor metal complex sodium trans-dinitrobis(2,4-pentanedionato)cobalt(III). The subject matter of the present application differs from that of D16 by Group T of the compounds according to the present application compared to the nitro groups in the compound according to D16. In the compounds according to the present application, Group T is bonded to the metal atom only by a dative bond. This is not the case with the nitro groups in D16.

The problem addressed by the present application is that of providing new compounds for fighting tumors.

The use according to Claims 1 to 4 and the pharmaceutical compositions according to Claims 5 and 6 are not obvious from the prior art and therefore involve an inventive step.

Further observations/objections:

The content of D15 and D16 should be evaluated in the description (PCT Rule 5.1(a)(ii)).

The description should be brought into line with the amended claims.